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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,879	06/27/2003	Lieven Stuyver	BJS-2551-123	5237

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EXAMINER	
PENG, BO	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/606,879	STUYVER ET AL.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-32 and 34* is/are pending in the application.

4a) Of the above claim(s) *18-27,30-32 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-17,28 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/20/2006&6/14/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment filed June 14, 2007. Claims 15-32 and 34 are pending. Claims 18-27, 30-32 and 34 are nonelected. Claims 15-17, 28 and 29 are examined in the instant Office action.

Drawings

2. The objection to the Figure 1 is withdrawn in view of the amendment to the specification filed on June 14, 2007.

Information Disclosure Statement

3. The information disclosure statements submitted on December 20, 2006 and June 14, 2007 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner. The initialed and dated copies of Applicant's IDS form 1449 are attached to the instant Office action.

Claim Objection

4. The objection to Claims 15-17, 28 and 29 **is withdrawn** in view of the amendment to the claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. The rejection of Claims 15 and 16 under 35 U.S.C. 102(b) as being anticipated by McDonough (EP0569237A2, 1993) **is maintained**.

7. Applicant argues that the cited reference fails to teach each and every aspect of the claimed invention because HBV *serotype* is not *genotype,* and the *serotypes* do not correspond with single *genotypes,* with several *serotypes* encoded by more than one *genotype.* Applicant also submitted a table to show relationship between serotypes and genotypes. (Remarks, p. 11 and the attached table).

8. Applicant's argument is considered but is not convincing for following reasons: The examiner did not mistake HBV serotype for the genotype. As indicated in the previous office action, McDonough teaches a method of detecting HBVadw, which belongs to HBV genotype A based on the description of both McDonough (pp 11 and 12) and the instant specification (See p.23, l.1 and 2).

9. Regarding the newly submitted table, first, it is noted that Applicant does not indicate the source of the reference. Secondly, there are significant discrepancies in classification of HBV genotypes between the Table and the instant specification as originally filed (See p. 23, l.1-10, and Figure 1). For example, HBV*adw* is indicated as genotype C in the newly submitted table, but is indicated as genotype A in the specification (See p.23, l.1 and 2). Since "claims must be given their... interpretation consistent with supporting description" (In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000), the submitted a table of relationship between

serotypes and genotypes is not considered as a supporting description of the instant claims.

10. McDonough teaches a method of detecting HBVadw, which belongs to HBV genotype A (see pp 11 and 12), wherein the method comprises the all the active steps of the instant claims, including the step of amplifying HBV with oligonucleotides primers, and the step of hybridizing HBV nucleic acids obtained directly or amplified HBV nucleic acids. Since McDonough's reference teaches each and every aspect of the claimed invention, McDonough has anticipated the instant "method for determining the presence or absence of HBV genotype A in a biological sample". Therefore, the rejection is maintained.

35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The rejection of Claims 15-17, 28 and 29 under 35 U.S.C. 103(a) as being obvious over McDonough, Maertens (WO 94/12670) and Ashton-Rickard (1989), **is maintained** for the reasons of record.

13. Applicant argues that the cited art is describing different targets achieved by different processes. Specifically, Ashton-Rickardt and McDonough teaches whether HBV, and Maertens generally describes a method for genotyping various viruses where under HBV, but does not give any indication in which part of the genome the probes and primers should be construed.

With the present invention both the region (HBsAg) and specific primer and probes have been disclosed to provide a method to establish whether genotype A is present or not in a sample, eventually combined with the presence of other genotypes (Remarks, pp11 and 12).

14. Applicant's argument is considered but is not persuasive. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

15. Specifically, the cited art describes same HBV target and a line probe assay (LiPA) as the instant invention. Applicant has provisionally elected SEQ ID NO: 77 as HBV genotype A specific target sequence for examination. SEQ ID NO:77 is corresponding to codons 142-147 of HBsAg as indicated in Figure 1D of specification. Ashton-Rickardt teaches that α determine region of HBV genotype A is located between amino acid residues138-147. Thus, as indicated by the previous office action, the target site of the instant method is described by Ashton-Richardt, and is known and interested in the art. Moreover, Maertens teaches a line probe assay (LiPA) for genotyping viruses, such as HCV, HIV and HBV, present in biological samples (see P. 25). McDonough teaches a method of detecting HBV genotype A. Both Maerten and MaDonough teach all active steps of the instant claims. Thus, the cited art describes same HBV target and process as the instant claims.

16. Although the cited references do not explicitly teach the claimed primers, however, once the specific HBV target is known, it is within one of ordinary skill in the art to make the claimed

primers or equivalent thereof to successfully hybridize the HBV target. Absence any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in utilizing Maertens LiPA to detect HBV genotype A at of α determine region of HBV as taught by McDonough and Ashton-Rickardt. Therefore, the rejection is maintained.

Remarks

17. No claim is allowed. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph. D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

BP

Bo Peng, Ph.D.
August 31, 2007

Bruce Campell

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
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